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[54] **HEARING AID TRANSDUCER SUPPORT**

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[73] Assignee: **St. Croix Medical, Inc.**, Minneapolis, Minn.

[21] Appl. No.: **08/908,233**

[22] Filed: **Aug. 7, 1997**

Related U.S. Application Data

[63] Continuation-in-part of application No. 08/695,099, Aug. 7, 1996, Pat. No. 5,836,863.

[51] **Int. Cl.**[6] **A61F 2/18**; A61B 19/00; A04R 25/00

[52] **U.S. Cl.** **623/10**; 600/25; 606/130

[58] **Field of Search** 623/10, 11, 16; 600/25; 607/55, 56, 57; 606/60, 61, 130

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Primary Examiner—David J. Isabella
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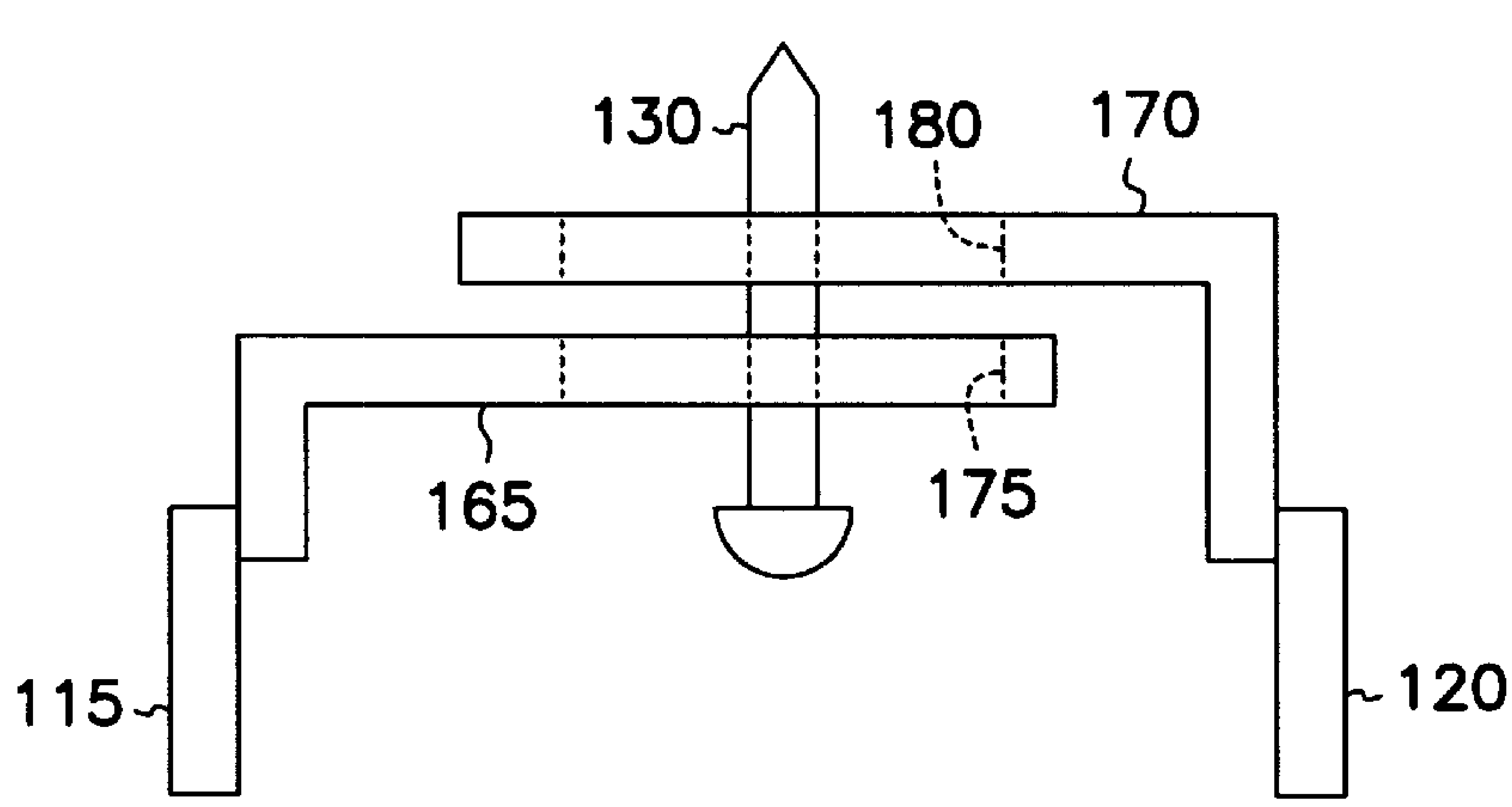
[57] **ABSTRACT**

A support for input and output transducers of a hearing aid is implanted in the middle ear. The support, which is attached to the mastoid bone, can be a single component or comprise two adjustable components. In one embodiment, an arm extends from the proximal end of the support towards an access hole created behind the outer ear, where the arm is attached for further stability. In another embodiment, the arm extends outside the access hole, where it is mounted subcutaneously to the mastoid bone with a mechanical fastener. The support provides positional adjustability, stability, and is invisible externally. The support can be a single bracket. The transducers are connected to an electronics unit. The electronics can be programmed or reprogrammed.

11 Claims, 8 Drawing Sheets



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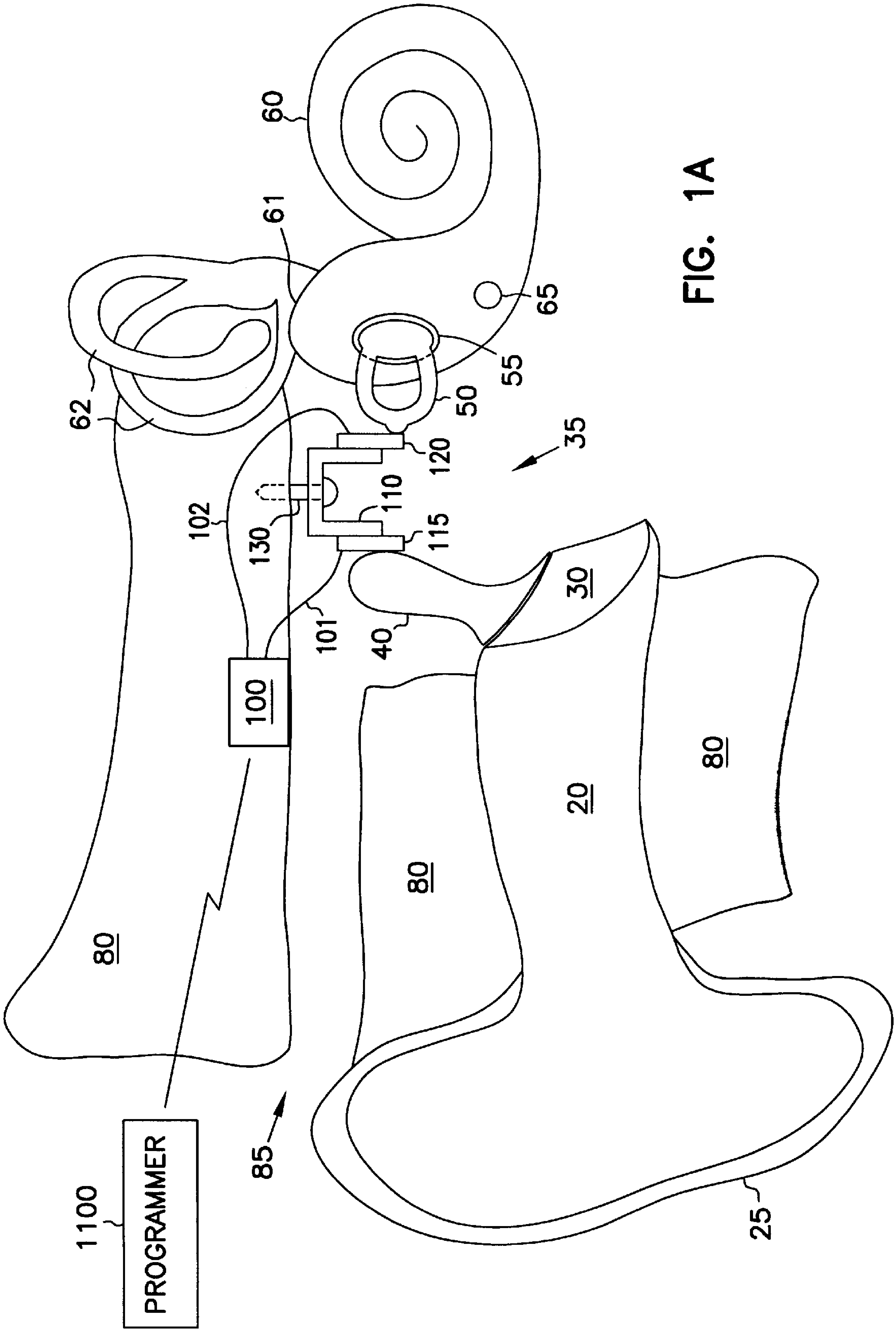
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FIG. 1A

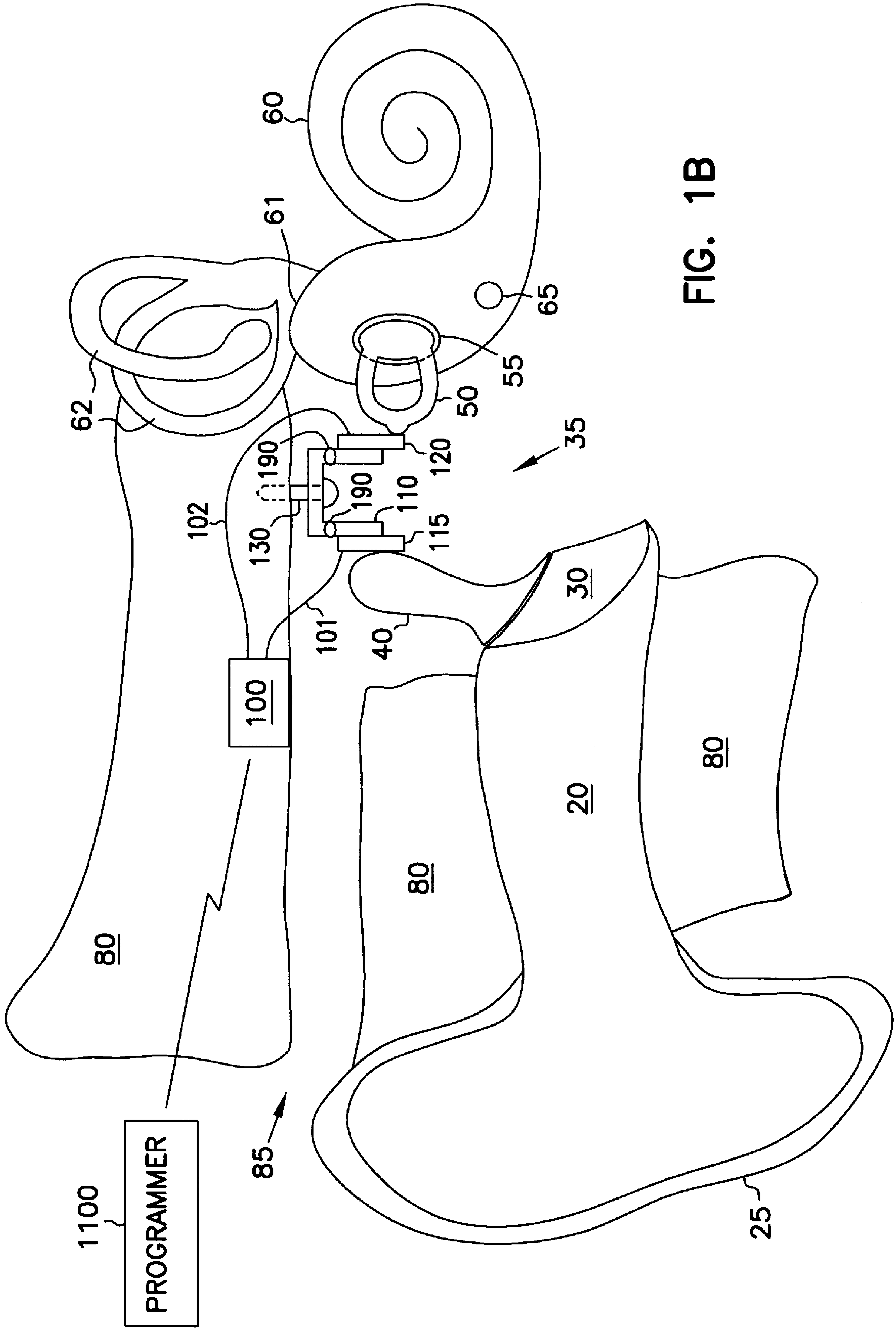
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FIG. 1B

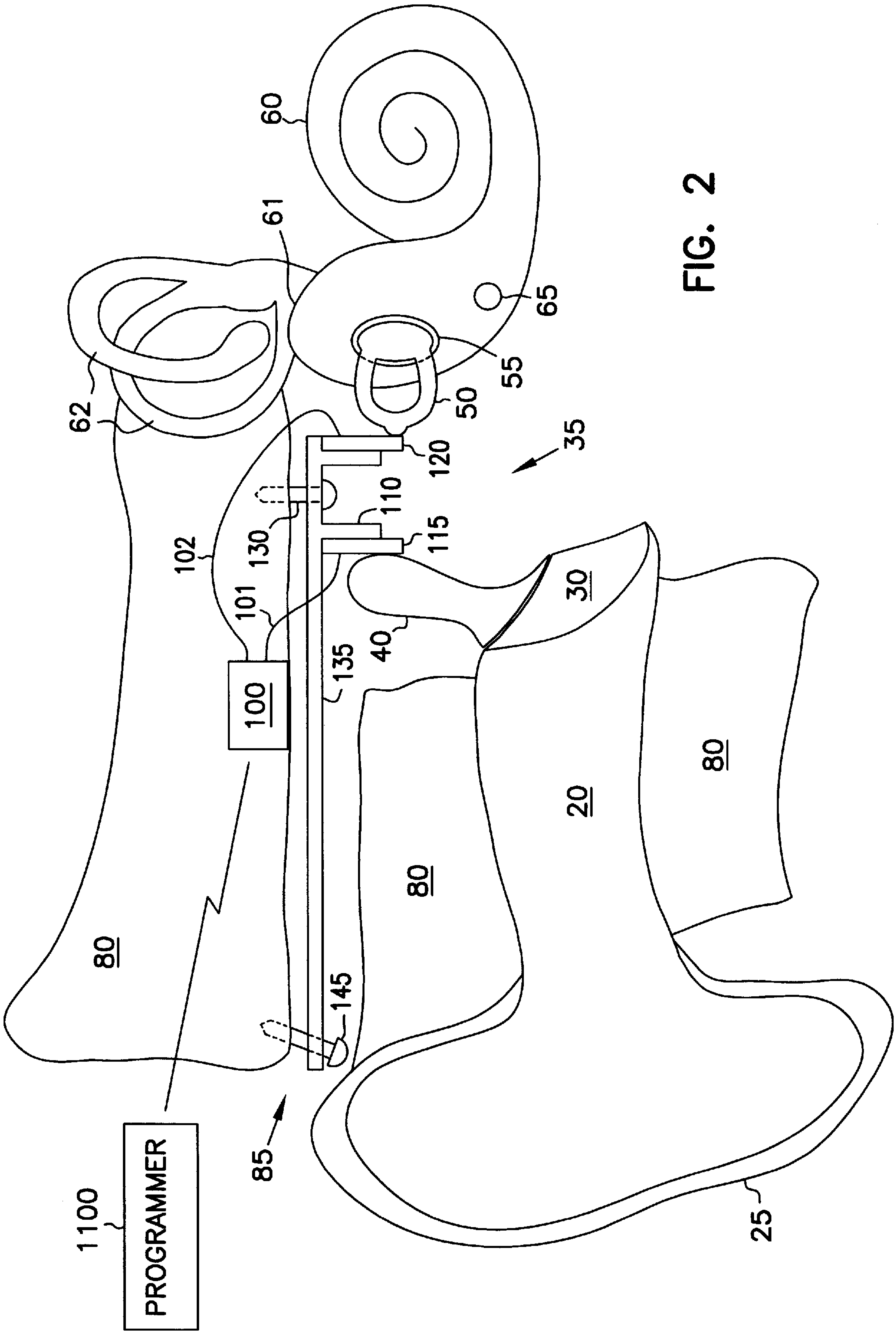
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FIG. 2

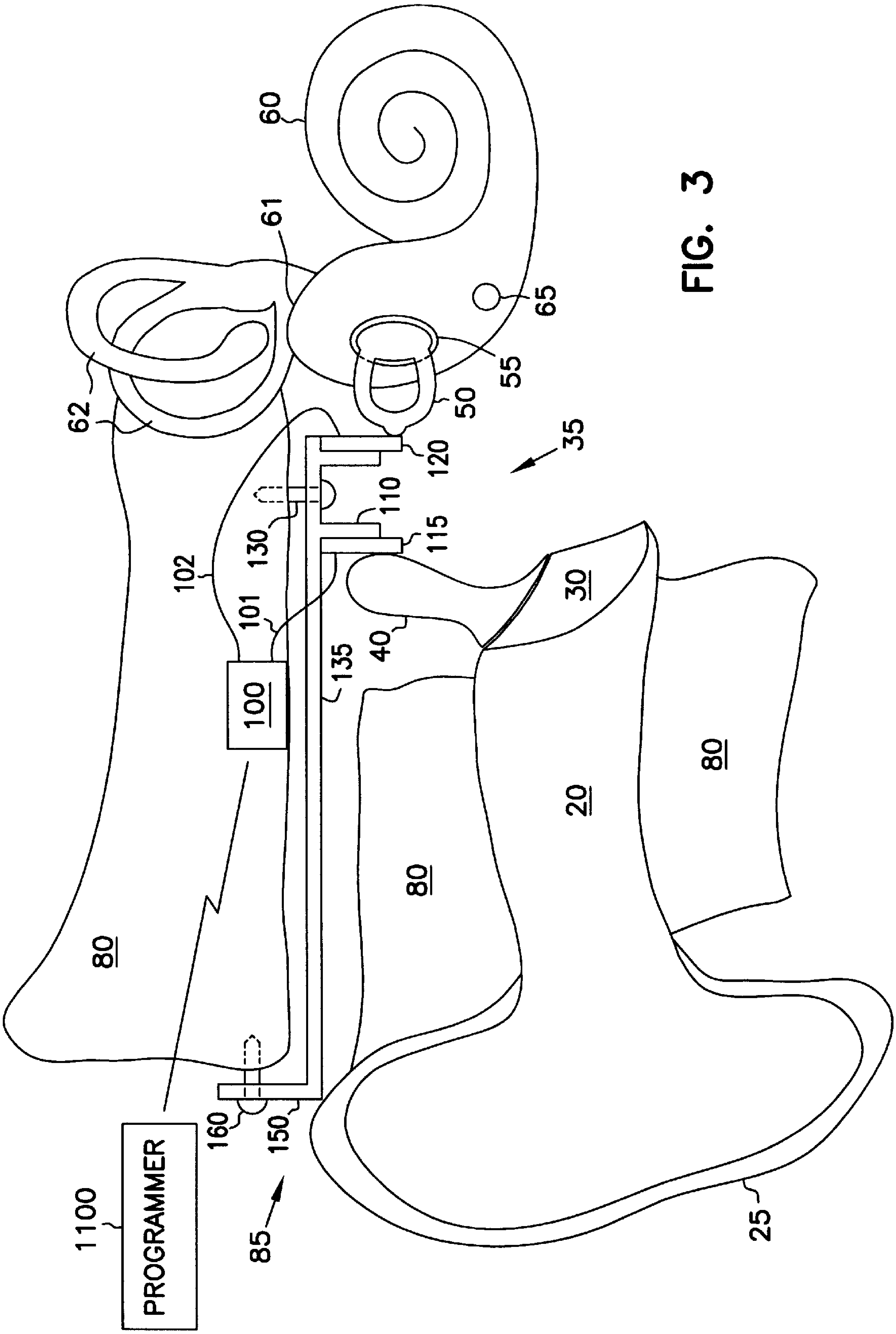
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FIG. 3

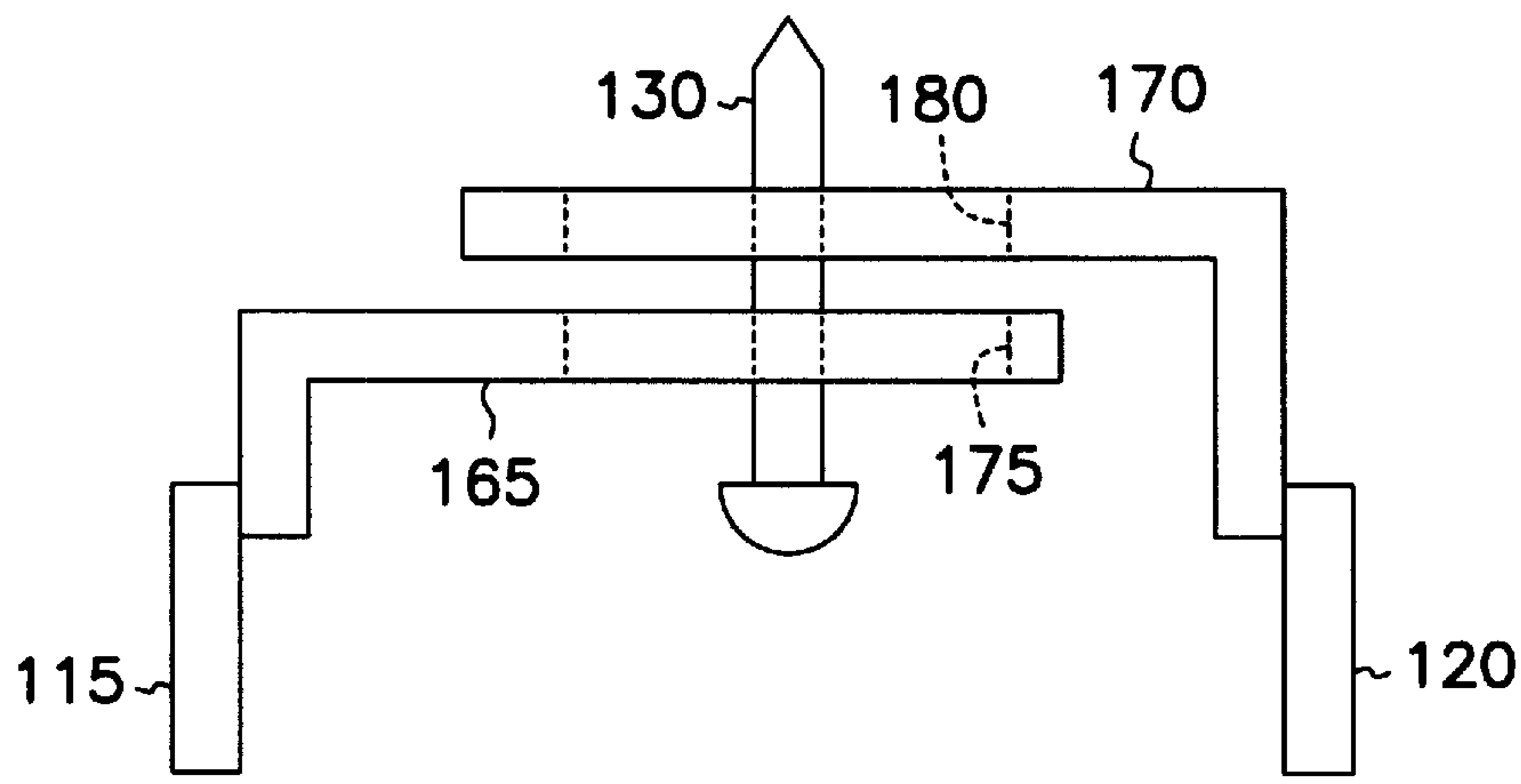

FIG. 4A

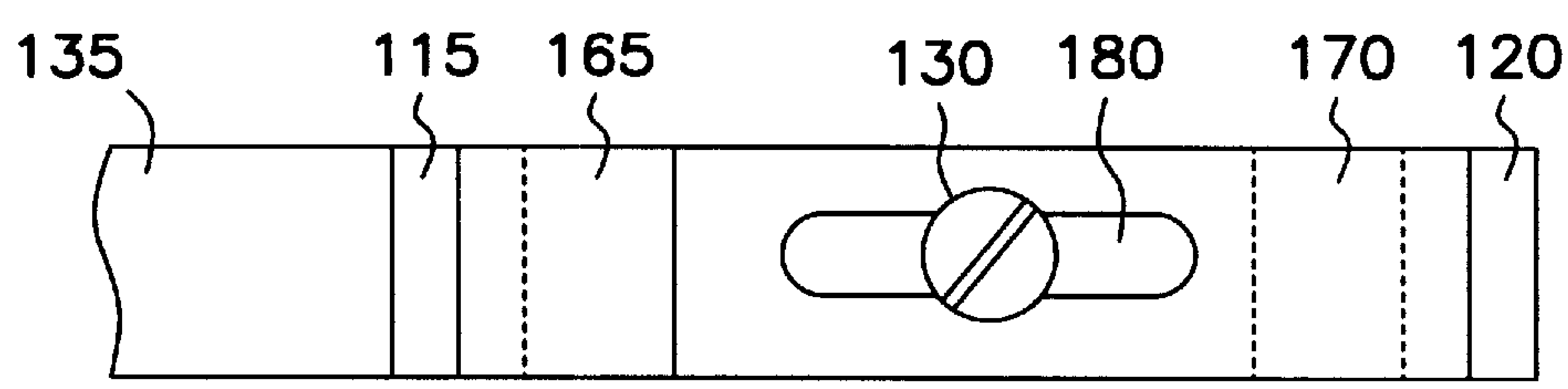

FIG. 4B

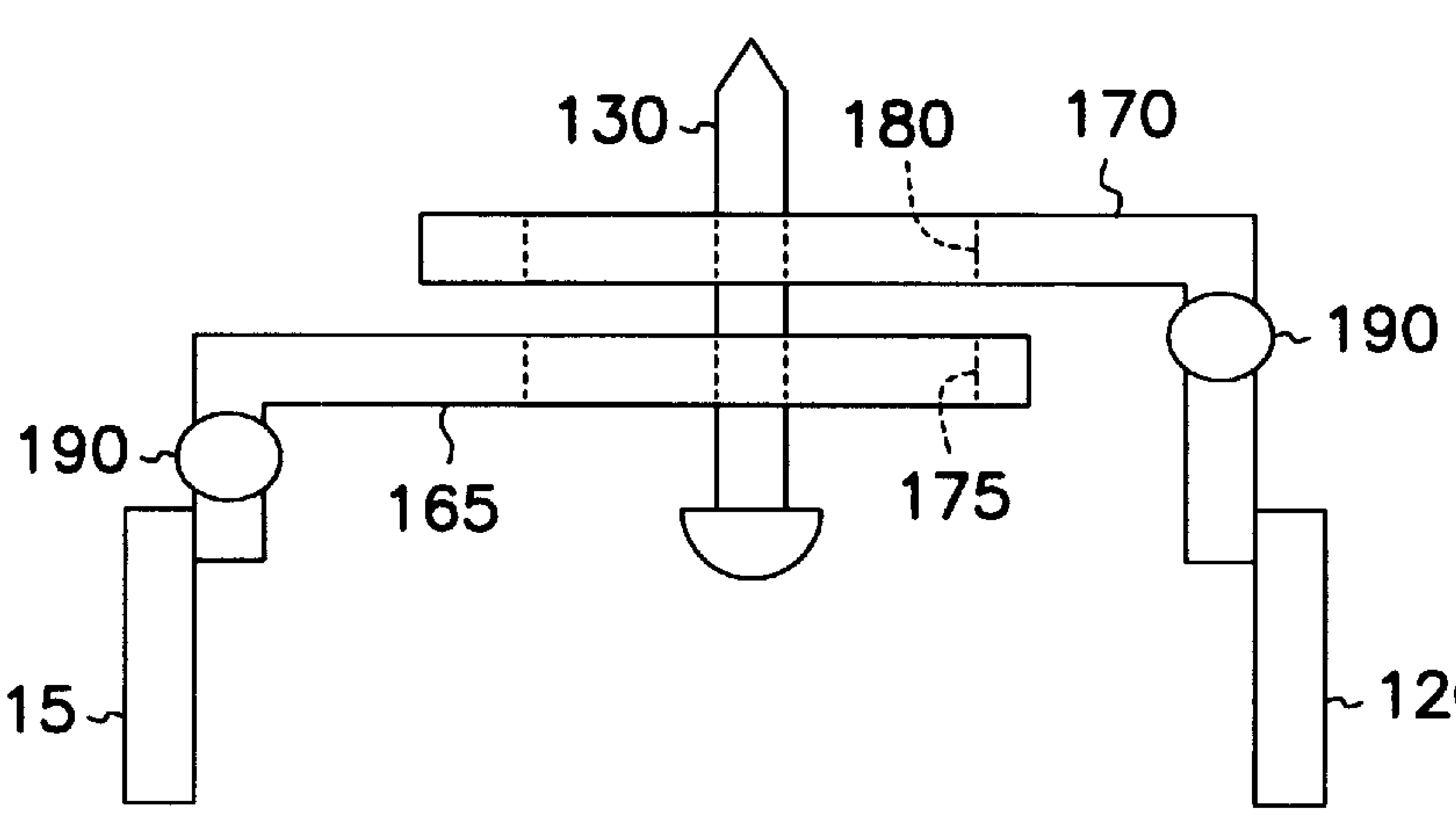

FIG. 4C

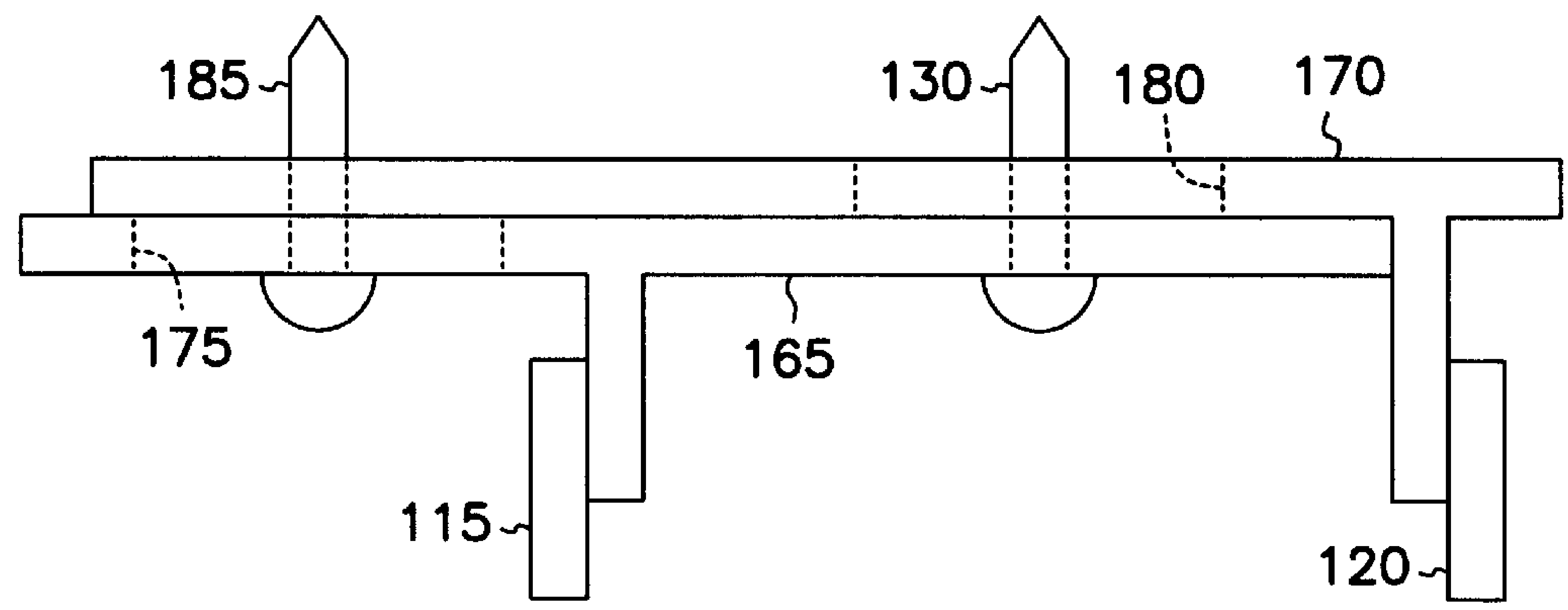

FIG. 5A

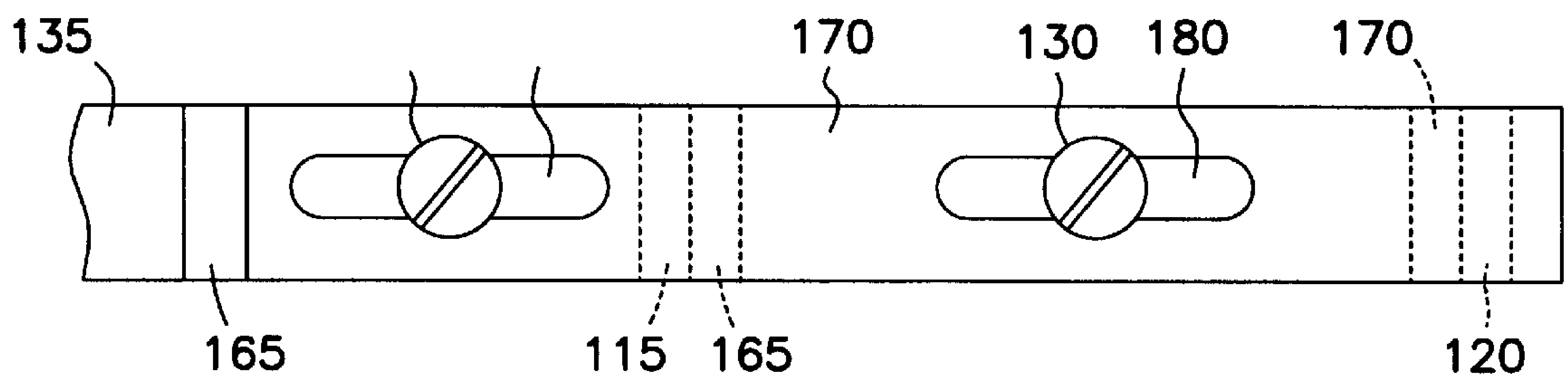

FIG. 5B

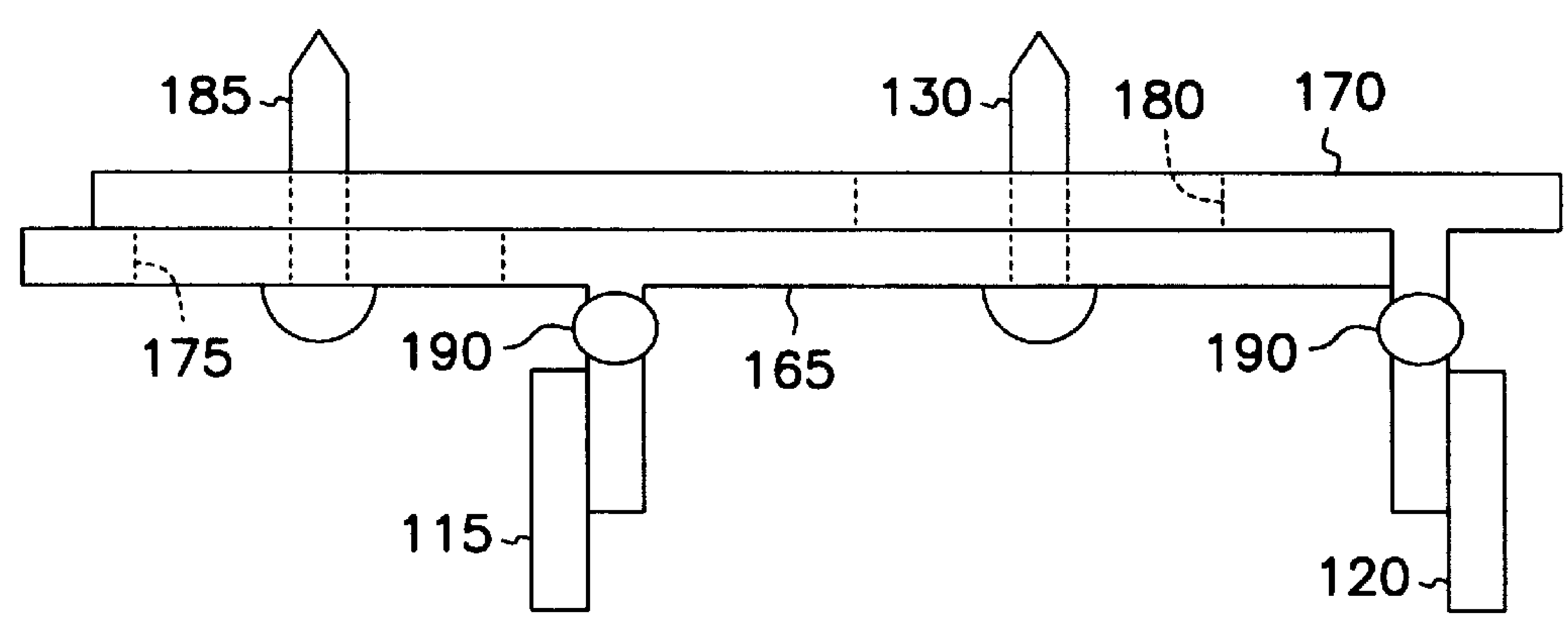

FIG. 5C

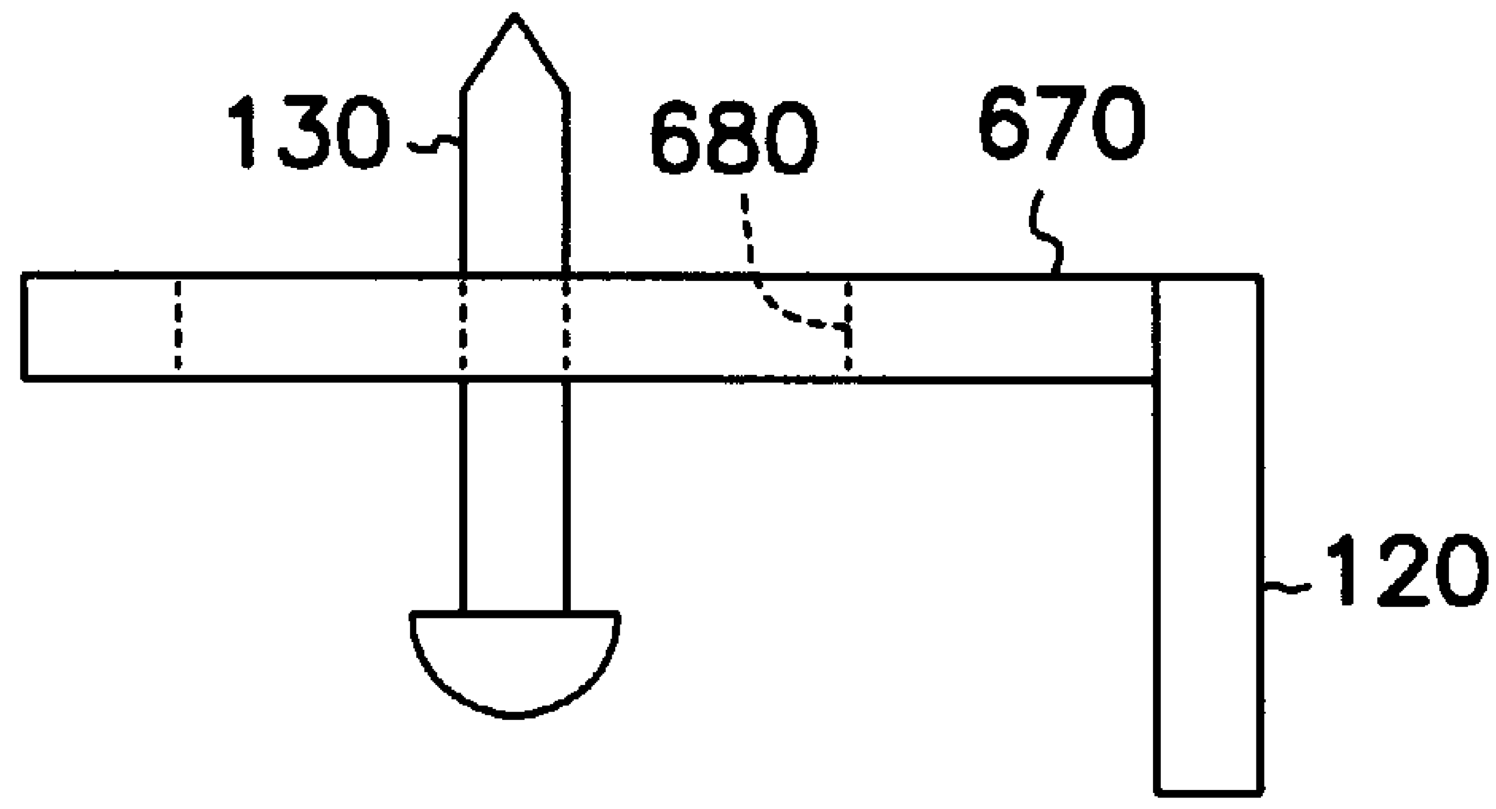

FIG. 6A

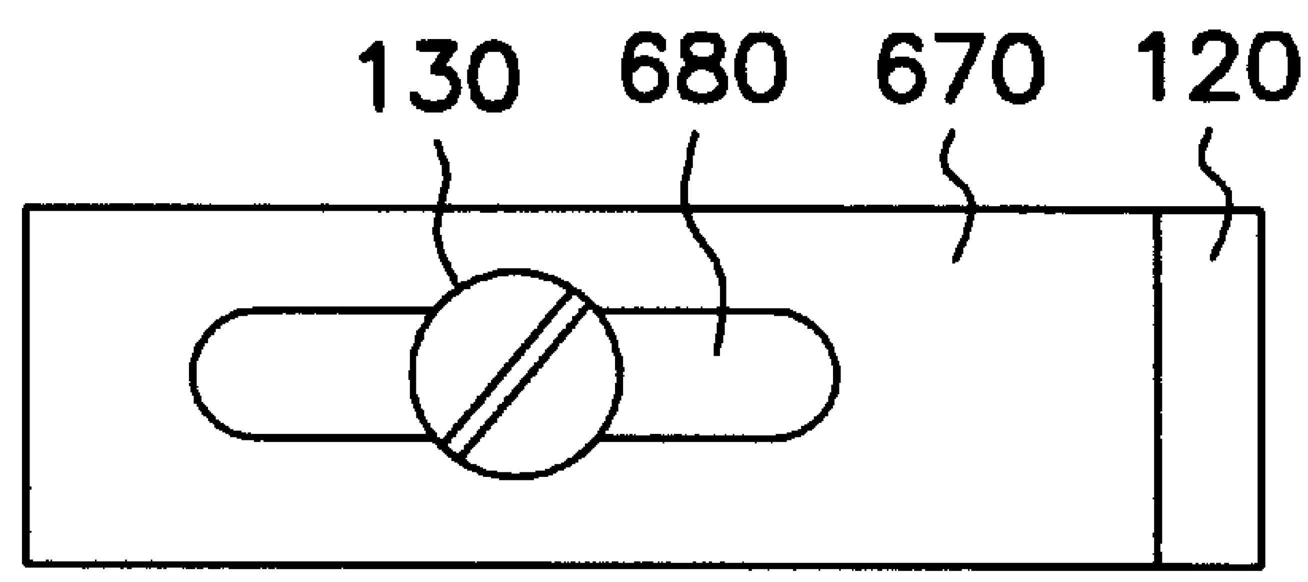

FIG. 6B

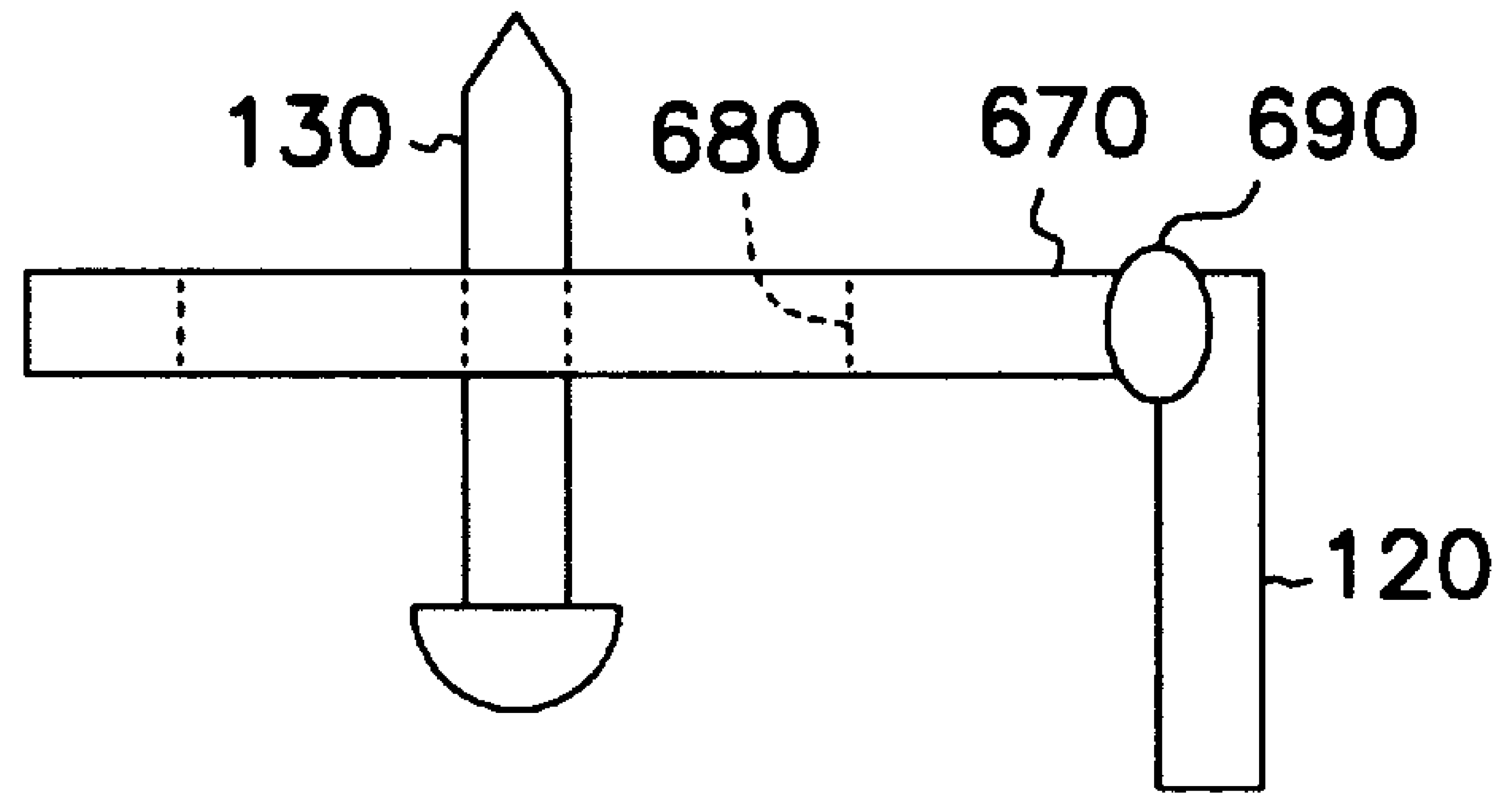

FIG. 6C

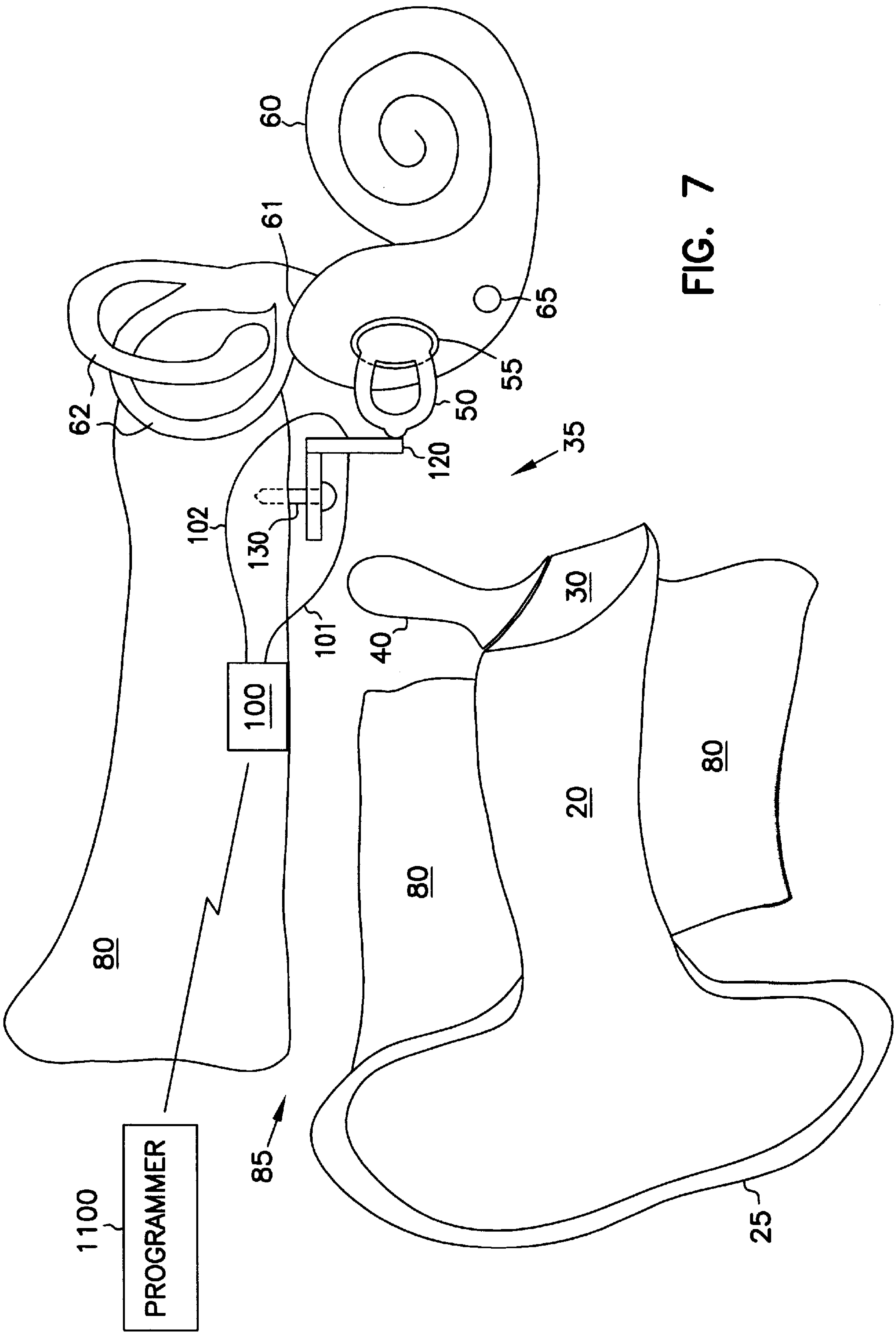
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FIG. 7

HEARING AID TRANSDUCER SUPPORT

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of U.S. patent application Ser. No. 08/695,099 now U.S. Pat. NO. 5,836, 863 entitled HEARING AID TRANSDUCER SUPPORT, filed on Aug. 7, 1996.

FIELD OF THE INVENTION

This invention relates to mounting implantable hearing aid transducers within the middle ear.

BACKGROUND

In an implantable hearing aid system, transducers within the middle ear engage an auditory element and transduce between electrical signals and mechanical vibrations. Middle ear hearing aid systems are not as susceptible to mechanical feedback as other types of systems. Such systems are more comfortable for the patient than other types of hearing aids, such as those placed directly in the external auditory canal. Transducers which contact an auditory element, such as one of the elements of the ossicular chain, require precise and reliable disposition within the middle ear. This is further complicated by anatomical variations among patients.

SUMMARY OF THE INVENTION

An implantable hearing aid (IHA) transducer support is mounted to the mastoid bone within a patient's middle ear region. Input and output transducers are coupled to respective mounting portions on a single support. An electronics unit of the IHA is not attached to the support, simplifying implantation and attachment of the IHA support and transducers. When repairs or adjustments, such as replacing a battery, need to be made to the electronics unit of the IHA, it is not necessary to remove or adjust the support.

In one embodiment, a support comprises a single component. Input and output transducers are coupled to respective mounting portions on opposite ends of the support prior to implantation. In a preferred embodiment, an arm extends from the support towards and into an access hole created behind the outer ear. The access hole is created, extending through the mastoid bone and into the patient's ear. The arm is attached to the mastoid bone at its proximal end, providing more stability to the support. In an even more preferred embodiment, the arm extends outside the access hole, where it is mounted subcutaneously to the mastoid bone with a bone screw or other mechanical fastener. In a further embodiment, universal connectors are placed between the support and mounting portions for each transducer. The universal connectors, such as ball and socket joints, allow further adjustability and 360 degree movement to position the transducers against respective auditory elements.

In another embodiment, the position of the transducers within the middle ear cavity may be adjusted by manipulating a mechanical fastener that affixes the support to the mastoid bone. In this embodiment, the support comprises two components. Each of the components has an opening. At least one of the openings comprises an adjustment slot. The mechanical fastener extends through mutually-aligned slots/openings on alternate support components within the middle ear region. The distance between the transducers and the angle between the transducers and the support may be independently adjusted by positioning the adjustment slots

with respect to the fastener. The resulting IHA support and transducers have positional stability and are invisible externally. In a further embodiment, universal connectors are placed between mounting portions for each transducer and each respective support component. The universal connectors, such as ball and socket joints, allow further adjustability and 360 degree movement to position the transducers against respective auditory elements.

In yet another embodiment, the position of the transducers within the middle ear region may be adjusted by manipulating two mechanical fasteners. In this embodiment, the support also comprises two components. Each component of the support has at least two adjustment slots or openings. Each of the two mechanical fasteners extends through mutually-aligned openings in opposite components. At least one of the two openings, through which a mechanical fastener extends, comprises a slot. The distance between the transducers is adjusted by positioning the adjustment slots/openings with respect to their respective fasteners. The resulting IHA support and transducers also have positional stability and are invisible externally.

In another embodiment of the invention the support includes a single bracket which mounts to a bone in or near the middle ear. One end of a transducer is mounted to single bracket support. The other end of the transducer is postioned on or near a bone in the ossicular chain.

The invention also provides an electronics unit to control the transducer and an external programmer to change the parameters of control for the electronics unit.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG **1A** is a schematic diagram illustrating a human auditory system in which an access hole is created in the mastoid, to which a single component dual transducer support is affixed.

FIG. **1B** is a schematic diagram illustrating a further embodiment of the invention shown in FIG. **1A**, in which ball and socket joints provide further adjustability of transducer position.

FIG. **2** is a schematic diagram illustrating a human auditory system, showing an alternate embodiment of the dual transducer support shown in FIG. **1A**.

FIG. **3** is a schematic diagram illustrating a human auditory system, showing an even further embodiment of the dual transducer support shown in FIG. **1A**.

FIG. **4A** is a schematic diagram illustrating yet another embodiment of a portion of the dual transducer support shown in FIGS. **1A**, **2**, and **3**, the support having transducers affixed to opposite sides and having one mechanical fastener with adjustment slots/openings.

FIG. **4B** is a plan view of the dual transducer support shown in FIG. **4A**.

FIG. **4C** is a further embodiment of the invention shown in FIG. **4A**, in which ball and socket joints provide further adjustability to transducer position.

FIG. **5A** is a schematic diagram illustrating yet another embodiment of a portion of the dual transducer support shown in FIGS. **1A**, **2**, and **3**, the support having transducers attached to opposite sides and having two mechanical fasteners with adjustment slots/openings.

FIG. **5B** is a plan view of the dual transducer support shown in FIG. **5A**.

FIG. **5C** is a further embodiment of the invention shown in FIG. **5A**, in which ball and socket joints provide further adjustability to transducer position.

FIG. **6A** is a diagram illustrating a single bracket transducer support embodiment having one mechanical fastener with adjustment slots/openings.

FIG. **6B** is a plan view of the transducer support shown in FIG. **6A**.

FIG. **6C** is a further embodiment of the invention shown in FIGS. **6A** and **6B**, in which ball and socket joints provide further adjustability for the transducer.

FIG. **7** is a schematic diagram illustrating a human auditory system, showing transducer support shown in FIGS. **6A** and **6B**.

DETAILED DESCRIPTION

The invention provides a transducer support, which is particularly advantageous when used in a middle ear implantable hearing aid system, such as a partial middle ear implantable (P-MEI) or total middle ear implantable (T-MEI) hearing aid system. A P-MEI or T-MEI hearing aid system assists the human auditory system in converting acoustic energy contained within sound waves into electrochemical signals delivered to the brain and interpreted as sound. FIG. **1A** illustrates generally the use of the invention in a human auditory system. Sound waves are directed into an external auditory canal **20** by an outer ear (pinna) **25**. The frequency characteristics of the sound waves are slightly modified by the resonant characteristics of the external auditory canal **20**. These sound waves impinge upon the tympanic membrane (eardrum) **30**, interposed at the terminus of the external auditory canal, between it and the tympanic cavity (middle ear) **35**. Variations in the sound waves produce tympanic vibrations. The mechanical energy of the tympanic vibrations is communicated to the inner ear, comprising cochlea **60**, vestibule **61**, and semicircular canals **62**, by a sequence of articulating bones located in the middle ear **35**. This sequence of articulating bones is referred to generally as the ossicular chain. Thus, the tympanic membrane **30** and ossicular chain transform acoustic energy in the external auditory canal **20** to mechanical energy at the cochlea **60**.

The ossicular chain includes three primary components: a malleus **40**, an incus (not shown), and a stapes **50**. The malleus **40** includes manubrium and head portions. The manubrium of the malleus **40** attaches to the tympanic membrane **30**. The head of the malleus **40** articulates with one end of the incus. The incus normally couples mechanical energy from the vibrating malleus **40** to the stapes **50**. The stapes **50** includes a capitulum portion, comprising a head and a neck, connected to a footplate portion by means of a support crus comprising two crura. The stapes **50** is disposed in and against a membrane-covered opening on the cochlea **60**. This membrane-covered opening between the cochlea **60** and middle ear **35** is referred to as the oval window **55**. Oval window **55** is considered part of cochlea **60** in this patent application. The incus articulates the capitulum of the stapes **50** to complete the mechanical transmission path.

Normally, prior to implantation of the invention, tympanic vibrations are mechanically conducted through the malleus **40**, incus, and stapes **50**, to the oval window **55**. Vibrations at the oval window **55** are conducted into the fluid-filled cochlea **60**. These mechanical vibrations generate fluidic motion, thereby transmitting hydraulic energy within the cochlea **60**. Pressures generated in the cochlea **60** by fluidic motion are accommodated by a second membrane-covered opening on the cochlea **60**. This second membrane-covered opening between the cochlea **60** and middle ear **35** is referred to as the round window **65**. Round window **65** is considered part of cochlea **60** in this patent application. Receptor cells in the cochlea **60** translate the fluidic motion into neural impulses which are transmitted to the brain and perceived as sound. However, various disorders of the tympanic membrane **30**, ossicular chain, and/or cochlea **60** can disrupt or impair normal hearing.

Hearing loss due to damage in the cochlea is referred to as sensorineural hearing loss. Hearing loss due to an inability to conduct mechanical vibrations through the middle ear is referred to as conductive hearing loss. Some patients have an ossicular chain lacking sufficient resiliency to transmit mechanical vibrations between the tympanic membrane **30** and the oval window **55**. As a result, fluidic motion in the cochlea **60** is attenuated. Thus, receptor cells in the cochlea **60** do not receive adequate mechanical stimulation. Damaged elements of ossicular chain may also interrupt transmission of mechanical vibrations between the tympanic membrane **30** and the oval window **55**.

Various techniques have been developed to remedy hearing loss resulting from conductive or sensorineural hearing disorder. For example, tympanoplasty is used to surgically reconstruct the tympanic membrane **30** and establish ossicular continuity from the tympanic membrane **30** to the oval window **55**. Various passive mechanical prostheses and implantation techniques have been developed in connection with reconstructive surgery of the middle ear **35** for patients with damaged ossicles. Two basic forms of prosthesis are available: total ossicular replacement prostheses (TORP), which is connected between the tympanic membrane **30** and the oval window **55**; and partial ossicular replacement prostheses (PORP), which is positioned between the tympanic membrane **30** and the stapes **50**.

Various types of hearing aids have been developed to compensate for hearing disorders. A conventional "air conduction" hearing aid is sometimes used to overcome hearing loss due to sensorineural cochlear damage or mild conductive impediments to the ossicular chain. Conventional hearing aids utilize a microphone, which transduces sound into an electrical signal. Amplification circuitry amplifies the electrical signal. A speaker transduces the amplified electrical signal into acoustic energy transmitted to the tympanic membrane **30**. However, some of the transmitted acoustic energy is typically detected by the microphone, resulting in a feedback signal which degrades sound quality. Conventional hearing aids also often suffer from a significant amount of signal distortion.

Implantable hearing aid systems have also been developed, utilizing various approaches to compensate for hearing disorders. For example, cochlear implant techniques implement an inner ear hearing aid system. Cochlear implants electrically stimulate auditory nerve fibers within the cochlea **60**. A typical cochlear implant system includes an external microphone, an external signal processor, and an external transmitter, as well as an implanted receiver and an implanted single channel or multichannel probe. A single channel probe has one electrode. A multichannel probe has an array of several electrodes. In the more advanced multichannel cochlear implant, a signal processor converts speech signals transduced by the microphone into a series of sequential electrical pulses of different frequency bands within a speech frequency spectrum. Electrical pulses corresponding to low frequency sounds are delivered to electrodes that are more apical in the cochlea **60**. Electrical pulses corresponding to high frequency sounds are delivered to electrodes that are more basal in the cochlea **60**. The nerve fibers stimulated by the electrodes of the cochlear implant probe transmit neural impulses to the brain, where these neural impulses are interpreted as sound.

Other inner ear hearing aid systems have been developed to aid patients without an intact tympanic membrane **30**, upon which "air conduction" hearing aids depend. For example, temporal bone conduction hearing aid systems produce mechanical vibrations that are coupled to the cochlea **60** via a temporal bone in the skull. In such temporal bone conduction hearing aid systems, a vibrating element can be implemented percutaneously or subcutaneously.

A particularly interesting class of hearing aid systems includes those which are configured for disposition principally within the middle ear **35** space. In middle ear implantable (MEI) hearing aids, an electrical-to-mechanical output transducer couples mechanical vibrations to the ossicular chain, which is optionally interrupted to allow coupling of the mechanical vibrations to the ossicular chain. Both electromagnetic and piezoelectric output transducers have been used to effect the mechanical vibrations upon the ossicular chain.

One example of a partial middle ear implantable (P-MEI) hearing aid system having an electromagnetic output transducer comprises: an external microphone transducing sound into electrical signals; external amplification and modulation circuitry; and an external radio frequency (RF) transmitter for transdermal RF communication of an electrical signal. An implanted receiver detects and rectifies the transmitted signal, driving an implanted coil in constant current mode. A resulting magnetic field from the implanted drive coil vibrates an implanted magnet that is permanently affixed only to the incus. Such electromagnetic output transducers have relatively high power consumption, which limits their usefulness in total middle ear implantable (T-MEI) hearing aid systems.

A piezoelectric output transducer is also capable of effecting mechanical vibrations to the ossicular chain. An example of such a device is disclosed in U.S. Pat. No. 4,729,366, issued to D. W. Schaefer on Mar. 8, 1988. In the '366 patent, a mechanical-to-electrical piezoelectric input transducer is associated with the malleus **40**, transducing mechanical energy into an electrical signal, which is amplified and further processed. A resulting electrical signal is provided to an electrical-to-mechanical piezoelectric output transducer that generates a mechanical vibration coupled to an element of the ossicular chain or to the oval window **55** or round window **65**. In the '366 patent, the ossicular chain is interrupted by removal of the incus. Removal of the incus prevents the mechanical vibrations delivered by the piezoelectric output transducer from mechanically feeding back to the piezoelectric input transducer.

Piezoelectric output transducers have several advantages over electromagnetic output transducers. The smaller size or volume of the piezoelectric output transducer advantageously eases implantation into the middle ear **35**. The lower power consumption of the piezoelectric output transducer is particularly attractive for T-MEI hearing aid systems, which include a limited longevity implanted battery as a power source.

This invention provides a support **110** for disposing transducers within the middle ear **35** for use in an implantable hearing aid (IHA). The invention is applicable for use with both P-MEI and T-MEI hearing aid systems. The support **110** is capable of carrying both input **115** and output transducers **120** on respective mounting portions. Thus, input **115** and output transducers **120** need not be separately introduced into the middle ear **35**. This allows for convenient implantation of both input **115** and output transducers **120** within the middle ear **35**. The electronics unit **100** of the IHA is separately implanted. This further eases implantation and repair or adjustment to the electronics unit **100** of the IHA. Maintenance and repairs, such as changing a battery in the electronics unit **100** of the IHA, are easily made without removing the support **110**.

For implantation of hearing aid components, an access hole **85** is created in a region of the temporal bone known as the mastoid **80**. An incision is made in the skin covering the mastoid **80**, and an underlying access hole **85** is created through the mastoid **80** allowing external access to the middle ear **35**. The access hole **85** is located approximately posterior and superior to the external auditory canal **20**. By placing the access hole **85** in this region, transducers **115** and **120** affixed to a support **110** within the ear cavity **35** can be placed on approximately the same planar level as the auditory elements **40** and **50**, which they engage.

In one embodiment, as shown in FIG. **1**A, a single component support **110** is implanted into the middle ear cavity **35**. Input and output transducers **115** and **120**, respectively, are each affixed to the support **110** prior to implantation. One embodiment of the support **110** is illustrated generally in FIG. **1**A, comprising one component. However, it is to be understood that the component can be fabricated in multiple parts and coupled together, mechanically or otherwise, to produce a single component support **110**. The shape of the support **110** is not critical, provided that the support **110** allows both transducers to be mounted on it, preferably one transducer on each end. However, other configurations are possible, depending on patient anatomy and other factors. The support can be a U-shaped component, as shown in FIG. **1**A, or a rectangular shaped component, among other possibilities. One consideration in determining the shape of support **110** is that the spacing between an input transducer **115** and an output transducer **120** disposed on the support **110** is approximately 10 to 20 millimeters, varying depending on the anatomical requirements of the patient.

In this embodiment, at least one input transducer **115** is affixed to a first mounting portion on a proximal end of the support **110**. The input transducer **115** mechanically engages at least one auditory element, such as the malleus **40**, preferably on the body of the malleus **40** at a force of approximately 10 dynes. At least one output transducer **120** is also affixed to a second mounting portion on a distal end of the support **110**. The output transducer **120** is coupled to at least one auditory element, such as the stapes **50**, preferably on the head of the stapes **50** at a force of approximately 10 dynes. The transducers **115** and **120** comprise any type of transducer well known to one skilled in the art. In one embodiment, transducers **115** and **120** are ceramic piezoelectric bi-element transducers. Input transducer **115** transduces mechanical energy from vibration of an auditory element, such as the malleus **40**, into an electrical signal to the electronics unit **100**, which is preferably implanted in the mastoid **80**. The electronics unit **100** provides an amplified version of the electrical signal to the output transducer **120**. In response to this amplified electrical signal, the output transducer **120** produces a resulting mechanical vibration, which is coupled to an auditory element such as the stapes **50**. The electronics unit **100** is electrically connected to input transducer **115** and output transducer **120** by any convenient technique, indicated schematically as leads **101** and **102**, respectively.

The support **110** is also capable of receiving at least one bone screw **130**. The bone screw **130** secures the support **110** to the mastoid **80**. The bone screw **130** comprises any biocompatible material, and preferably is self-tapping; if so, it is captured by the support **110** and/or an opening created by the bone screw in the mastoid **80**, as well known to one skilled in the art. The support **110** also comprises any biocompatible material. Examples of biocompatible materials include titanium, stainless steel, certain ceramics (ex. alumina), certain polymers (ex. polycarbonates), and other materials well known to one skilled in the art. Furthermore, the bone screw **130** can be any type of screw well known to one skilled in the art, such as an orthopedic bone screw, a torx head screw, a single or double slotted head screw. To reduce the number of components handled during implantation of the invention, the support **110** is prefereably adapted to receive and hold the bone screw **130** such that the combination can be placed against the mastoid **80** as a single unit. Any suitable known technique, such as pre-threading or otherwise shaping the support **110** in accordance with known practices, is suitable.

In this embodiment, the incus is removed to prevent feedback of mechanical vibrations from the output transducer **120** to the input transducer **115** through the incus. By affixing the support **110** to mastoid, by a bone screw **130** or other fastener, such as a biocompatible adhesive, mechanical vibrations of the output transducer **120** are not transmitted back to the input transducer **115** through the support **110**.

In a further embodiment, as shown in FIG. 1B, universal connectors **190** are placed between mounting portions for each transducer **115**, **120** and the main support **110**. The universal connectors **190**, such as ball and socket joints, allow further adjustability and 360 degree movement to position the transducers **115** and **120** against respective auditory elements **40** and **50**.

In another further embodiment, as shown in FIG. **2**, the support **110** further comprises an arm **135**, extending from the support **110** towards the outer ear **35** through the access hole **85**. A bone screw **145** secures the arm **135** to the mastoid **80** and provides added stability to the support **110**. The arm **135** comprises any biocompatible material and is approximately one inch in length, extending approximately to the entrance of the access hole **85** created behind the outer ear **25**. The bone screw **145** used to affix the arm **135** to the mastoid **80** is of a similar type as the bone screw **130** used to affix the support **110** to the mastoid **80**. The arm **135** also allows for easy insertion of the support **110** into the access hole **85** and the middle ear **35**.

In an even further embodiment, as shown in FIG. **3**, the support **110** further comprises a lip **150**, extending outside the entrance of the access hole **85** from the arm **135**, where it is mounted subcutaneously to the mastoid bone **80** with a bone screw **160**. The lip **150** extends outward radially from the proximal end of arm **135**. The bone screw **160** used to attach the arm **135** to the mastoid bone **80** is of a similar type as the bone screw **130** used to attach the support **110** to the mastoid bone **80**. This embodiment increases support **110** stability and eases implantation, due to the addition of the arm **135** and lip **150**. However, the arm **135** can be integrally-fabricated with the lip **150**, so that they are one piece as in other embodiments.

FIGS. 1A, 1B, **2**, and **3** also include a programmer **1100**. The programmer shown includes an external (i.e., not implanted) programmer **1100** communicatively coupled to an external or implantable portion of the hearing assistance device, such as electronics unit **100**. Programmer **1100** includes hand-held, desktop, or a combination of hand-held and desktop embodiments, for use by a physician or the patient in which the hearing assistance device is implanted.

In one embodiment, each of programmer **1100** and the hearing assistance device include an inductive element, such as a coil, for inductively-coupled bi-directional transdermal communication between programmer **1100** and the hearing assistance device. Inductive coupling is just one way to communicatively couple programmer **1100** and the hearing assistance device. Any other suitable technique of communicatively coupling programmer **1100** and the hearing assistance device may also be used including, but not limited to, radio-frequency (RF) coupling, infrared (IR) coupling, ultrasonic coupling, and acoustic coupling.

In one embodiment, the signals are encoded using pulse-code modulation (PCM), such as pulse-width telemetry or pulse-interval telemetry. In pulse-width telemetry, communication is by short bursts of a carrier frequency at fixed intervals, wherein the width of the burst indicates the presence of a "1" or a "0". In pulse-interval telemetry, communication is by short fixed-length bursts of a carrier frequency at variable time intervals, wherein the length of the time interval indicates the presence of a "1" or a "0". The data can also be encoded by any other suitable technique, including but not limited to amplitude modulation (AM), frequency modulation (FM), or other communication technique.

The data stream is formatted to indicate that data is being transmitted, where the data should be stored in memory (in the programmer **1100** or the hearing assistance device), and also includes the transmitted data itself. In one embodiment, for example, the data includes an wake-up identifier (e.g., 8 bits), followed by an address (e.g., 6 bits) indicating where the data should be stored in memory, followed by the data itself.

In one embodiment, such communication includes programming of the hearing assistance device by programmer **1100** for adjusting hearing assistance parameters in the hearing assistance device, and also provides data transmission from the hearing assistance device to programmer **1100**, such as for parameter verification or diagnostic purposes. Programmable parameters include, but are not limited to: on/off, standby mode, type of noise filtering for a particular sound environment, frequency response, volume, gain range, maximum power output, delivery of a test stimulus on command, and any other adjustable parameter. In one embodiment, certain ones of the programmable parameters (e.g., on/off, volume) are programmable by the patient, while others of the programmable parameters (e.g., gain range, filter frequency responses, maximum power output, etc.) are programmable only by the physician.

In another embodiment, the single component support **110**, shown in FIGS. **1** to **3**, is replaced with an adjustable support **100**, having two components **170** and **165**, as shown in FIGS. **4A** and **4B**. In this embodiment, the support **110** allows for independent adjustments of the distance between the input and output transducers **115** and **120**, respectively, and the angle between the transducers **115** and **120** with respect to the support mounting screw **130**. Such independent adjustments allow multiple auditory elements, such as the malleus **40** and the stapes **50**, to be properly coupled to the input and output transducers **115** and **120**, respectively, in a patient population having varying anatomical features within the middle ear **35**.

The shape of components **165** and **170** in this embodiment is not critical, provided that the support **110** allows both transducers to be mounted on it, preferably one transducer on each end. However, other configurations are possible, depending on patient anatomy and other factors. Components **165** and **170** can be L-shaped, as shown in FIG. **4A**, rectangular-shaped, or any other shape that facilitates mounting of transducers **115** and **120**. Each support component **165** or **170** can be fabricated as multiple parts coupled together, mechanically or otherwise, to produce a single component **165** or **170**.

A mechanical fastener, such as a bone screw **130**, couples the support components **165** and **170** together and affixes the support **110** to the mastoid bone **80**. However, other types of fastener techniques can be used. For example, one of the two components **165**, **170** can be shaped with a flanged arm extending from it, such that the arm extends through the adjustment opening on the opposite component, coupling it with the flange. Each support component **165** and **170** has an opening **175** and **180**. At least one of the openings **175**, **180** comprises a slot. The bone screw **130** extends through mutually-aligned openings **175** and **180** on alternate support components **165** and **170** within the middle ear region **35**. The distance between the transducers **115** and **120** and the angle between the transducers **115** and **120** with respect to the bone screw **130** are independently adjusted by positioning of the adjustment slots **175** and **180** with respect to the bone screw **130**. Adjustment slots **175** and **180** operate by slidable, longitudinal positioning of support components **165** and **170** with respect to each other. The adjustment slots **175** and **180** also operate by radial positioning of each support component **165**, **170** with respect to the bone screw **130**. The resulting IHA support and transducers have positional stability and are invisible externally. Other types of adjustment techniques can be used in place of adjustment slots **175** and **180**.

In a further embodiment, as shown in FIG. **4**C, universal connectors **190** are placed between mounting portions for each transducer **115**, **120** and the respective main support component **165**, **170**. The universal connectors **190**, such as ball and socket joints, allow further adjustability and 360 degree movement to position the transducers **115** and **120** against respective auditory elements **40** and **50**.

In yet another embodiment, the position of the transducers **115** and **120** is adjusted by manipulating two adjustment slots **175** and **180** within the middle ear region **35**, as shown in FIGS. **5**A and **5**B. In this embodiment, the support also comprises two components **165** and **170**. Again, each support component **165** or **170** can be fabricated in multiple parts and coupled together, mechanically or otherwise, to produce a single component **165** or **170**. Each support component **165** and **170** has at least one adjustment slot **175** and **180**, respectively. Two mechanical fasteners **130** and **185** extend through both support components **165** and **170** and respective mutually-aligned adjustment slots **175** and **180** on alternate support components **165**, **170** within the middle ear region **35**. The distance between the transducers **115** and **120** is adjusted by positioning of the adjustment slots **175** and **180**. The resulting IHA support and transducers also have positional stability and are invisible externally.

The shape of the two support components **165** and **170** in this embodiment is not critical, provided that the support **110** allows both transducers **115** and **120** to be mounted on it, preferably one transducer **115**, **120** on each end. However, other configurations are possible, depending on patient anatomy and other factors. Each component **165**, **170** can be L-shaped, modified L-shaped, as shown in FIG. **5**A, rectangular-shaped, or any other shape that facilitates mounting of transducers **115** and **120** to the support **110**. A bone screw **130** couples the two components **165** and **170** together and affixes the support **110** to the mastoid bone **80**, through an adjustment slot **180** on one component **170**. Another screw **185** couples the support components **165** and **170** together through a second adjustment slot **175**. This screw **185** comprises a similar material as the bone screw **130** that affixes the support **110** to the mastoid **80**, and it can also attach to the mastoid bone **80** for added stability. The distance between the transducers **115** and **120** is adjusted by positioning of the adjustment slots **175** and **180**. The adjustment slots **175** and **180** operate by allowing slidable, longitudinal positioning of the two components **165** and **170** with respect to each other. Depending on the fabrication of the components **165** and **170** and their respective adjustment slots **175** and **180**, the distance between the transducers **115** and **120** is adjustable by approximately 5 millimeters in either direction. The resulting IHA support and transducers have positional stability and are invisible externally. As with other embodiments, other types of adjustment techniques can be used in place of adjustment slots **175** and **180**.

In a further embodiment, as shown in FIG. **5**C, universal connectors **190** are placed between mounting portions for each transducer **115**, **120** and the respective main support component **165**, **170**. The universal connectors **190**, such as ball and socket joints, allow further adjustability and 360 degree movement to position the transducers **115** and **120** against respective auditory elements **40** and **50**.

FIGS. **6**A, **6**B, and **6**C show a single bracket support **670** having a transducer attached to the single bracket support **670**. The single bracket support **670** includes an opening **680**. A bone screw **130** passes through the oblong opening **680** and allows for independent adjustment of the distance between the support mounting screw **130**, which is typically a bone screw, and the transducer **120**. Such adjustment allows flexibility in that the single bracket support can be mounted with respect to different auditory elements, such as the malleus **40** and the stapes **50**, respectively, in a patient population having varying anatomical features within the middle ear **35**.

The shape of single bracket support **670** in this embodiment is more or less a flat plate. The transducer **120** is coupled to the flat plate either adhesively, mechanically or otherwise, to produce a single component. It should be noted that other configurations are possible, depending on patient anatomy and other factors. An L-shaped bracket **170**, such as is shown in FIG. **4**A, a rectangular-shaped bracket, or any other shaped bracket that facilitates mounting of transducer **120** can be used in place of the single bracket support **670**. The bone screw **130**, couples the single bracket support **670** to the mastoid bone **80**. Other types of fastening techniques can also be used. For example, single bracket support **670** can be shaped with a flange that could be attached to the mastoid bone **80**. The single bracket support **670** can be moved linearly and rotated with respect to the bone screw **130** to position the transducer **120** in a selected position with respect to one of the elements of the middle ear.

FIG. **6**C shows an embodiment having a universal connector **690** placed between the transducer **120** and the single bracket support **670**. The universal connector **690** may also be placed between the two portion of the single bracket support **670**. The universal connector **690**, such as a ball and socket joint, allows further adjustability and 360 degree movement to position the transducer **120** against respective auditory elements **40** and **50**.

FIG. **7** is a schematic diagram illustrating a human auditory system, showing transducer support shown in FIGS. **6**A and **6**B. In FIG. **7**, the bone screw **130** is attached to the mastoid bone **80**. The transducer **120** is adjustably in contact with the stapes **40**. It should be noted that the transducer **120** could also be adjustably in contact with the malleus **50**. Many elements of FIG. **7** are repeated from the previous FIGS. **1**A, **1**B, **2**, and **3**. For description of these repeated elements please refer to the description related to FIGS. **1**A, **1**B, **2**, and **3**.

We claim:

1. A support system for mounting a transducer within a middle ear into engagement with an ossicular element, the support system comprising:

a bracket shaped for implantation within the middle ear, said bracket having a portion with an opening therein suitable for receipt of a bone attachment mechanism, and a transducer attaching portion for attaching a portion of a transducer to the bracket so that another portion of the transducer is engageable with an ossicular element; and

a bone attachment mechanism sized for placement through the bracket opening and engagement with a portion of the bracket for affixing the bracket to the mastoid bone, the location of the transducer attaching portion with respect to the bone attachment mechanism being adjustable.

2. The support system of claim **1** wherein the bone attachment mechanism is a bone screw which passes through the opening in the bracket.

3. An implantable hearing system for mounting within a middle ear, the system comprising:

an adjustable bracket shaped for implantation within the middle ear, said bracket having a portion with an opening therein suitable for receipt of a bone attachment mechanism therethrough and a transducer attaching portion for attachment of a transducer thereto so that a portion of the transducer is also positionable for direct engagement with an ossicular element;

a transducer coupled to said bracket at the transducer attaching portion;

a bone attachment mechanism sized for use with the bracket opening for affixing the bracket to the mastoid bone, the position of the transducer with respect to the bone attachment mechanism being adjustable; and

an electronics unit electrically coupled to the transducer.

4. The implantable hearing system of claim **3**, in which the transducer inputs a signal to the electronics unit.

5. The implantable hearing system of claim **3**, in which the electronics unit outputs a signal to the transducer.

6. The implantable hearing system of claim **3** further comprising a programmer communicatively coupled to the electronics unit.

7. The implantable hearing system of claim **3** wherein the bone attachment mechanism is a bone screw which passes through the opening in the bracket.

8. The implantable hearing system of claim **7** wherein the bracket further includes a universal joint located between a portion of the bracket and the transducer to adjust a position of the transducer relative to a portion of the bracket.

9. The support system of claim **1** wherein the bracket further includes a universal joint located on a portion of the bracket between the opening for the bone attachment mechanism and the transducer attaching portion, the universal joint comprising means for adjusting the position of the transducer attaching portion relative to the opening.

10. An implantable hearing system for mounting within a middle ear, the system comprising:

an adjustable bracket, which is generally L-shaped in use, for implantation within the middle ear, said bracket having a portion with an elongate opening therein suitable for receipt of a bone attachment mechanism therethrough and a transducer attaching portion for attachment of a transducer thereto so that a portion of the transducer is also positionable for direct engagement with an ossicular element;

a transducer coupled to said bracket at the transducer attaching portion using a universal joint to allow adjustment of the transducer relative to the bracket;

a bone attachment mechanism sized for use with the bracket opening for affixing the bracket to the mastoid bone, the position of the transducer with respect to the bone attachment mechanism being adjustable due to the positioning of the bone attachment mechanism within the elongate opening; and

an electronics unit electrically coupled to the transducer.

11. The implantable hearing system of claim **10** wherein the bracket further includes a universal joint located between the bracket elongate opening and the bracket transducer attaching portion to provide means for further adjustment of a position of the transducer relative to a portion of the bracket.

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